

REMARKS

I. Status of the Application

Claims 1-48 are currently pending in the application. Claims 25-40 stand withdrawn as non-elected species due to a restriction requirement. Applicants gratefully acknowledge the withdrawal of the previous 35 U.S.C. § 103(a) rejection over the combination US 6,309,659 to Clokie and US 6,232,340 to Zhang, the withdrawal of the previous 35 U.S.C. § 103(a) rejection over the combination of Clokie, Zhang and US 5,290,552 to Sierra, and the withdrawal of the double patenting rejection over co-pending application 10/326,339. Claims 1-24 and 41-48 stand newly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Claims 1-15, 20-22, and 41-48 stand newly rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,309,659 to Clokie in view of US 6,623,729 to Park et al. (hereinafter "Park"). Claims 16-19 and 22-24 stand newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Clokie in view of Park and in further view of US 5,290,552 to Sierra et al. (hereinafter "Sierra").

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, independent claims 1 and 41 have been amended to remove the term "sample" in order to clarify that all of the claimed compound, not a sample of the compound, has no hydroxyl groups. The "dihydroxy compound" has also been replaced with the "dihydroxy starting material" in order to avoid confusion with the claimed "compound." Although the term "starting material" is not explicitly stated in the disclosure, one skilled in the art would understand that disclosed dihydroxy copolymers such as Pluronic comprise a starting material for the claimed compound. Accordingly, the amendments add no new matter.

Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place the application in condition for allowance.

II. Claims 1-24 and 41-48 Are Definite

At page 2, last paragraph of the instant Office Action, claims 1-24 and 41-48 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner is of the opinion that the term “sample” recited in independent claims 1 and 41 is unclear, so that the claims fails to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended claims 1 and 41 to remove the term “sample” and substitute the term “compound,” which clearly refers to the compound of formula (I). Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejection and allowance of claims 1-24 and 41-48.

III. Claims 1-15, 20-22 and 41-48 Are Not Obvious over Clokie in View of Park

At page 3, paragraph 3 of the instant Office Action, claims 1-15, 20-22 and 41-48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Clokie in view of Park. The Examiner is of the opinion that the subject claims are obvious in view of the combined teachings of Clokie and Park. Applicants respectfully traverse the rejection. A *prima facie* case of obviousness requires three showings:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Manual of Patent Examining Procedure, 8th ed., § 2142. These requirements of a *prima facie* case of obviousness are not met for the following rejections under 35 U.S.C. § 103(a).

Independent claim 1 is directed to a composition comprising a soluble product extracted from demineralized bone and a carrier comprising the block copolymer of formula (I). Independent claim 41 is directed to a composition comprising an osteogenic agent and a carrier comprising the block copolymer of formula (I). Clokie discloses compositions comprising PEG/polyoxypropylene/PEG block copolymer and demineralized bone powder (col. 1, lines 34-52). The Examiner asserts that it would be obvious to modify the block copolymer of Clokie to have a methoxy endgroup, such as in Park's methoxy-terminated PEG/polyester block copolymer. However, this combination is based upon improper hindsight reconstruction. "[I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious ... This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).

Clokie as the primary reference provides no suggestion of desirability to modify his teachings to arrive at the methoxy-terminated polymers of the present invention. The Examiner asserts that motivation to modify Clokie's teaching comes from Park, because Park teaches block copolymers useful for a similar purpose, that is, sustained release of active agents. Park teaches that it is desirable to cap one end of a block copolymer carrier with a methoxy group, and leave the other end free for covalent attachment of an active agent (col. 3, line 37 to col. 4, line 7, Figs. 2-4). However, Park fails to suggest the desirability of capping **both** ends of a block copolymer

carrier with methoxy groups because doing so would make it impossible to covalently attach an active agent to the copolymer, rendering the copolymer unsatisfactory for Park's intended purpose as a covalent carrier. Thus, the Examiner's combination of Clokie and Park does not teach or suggest the limitation wherein the claimed block copolymer is capped at both ends with methoxy groups. Nor does Park provide motivation for capping both ends of Clokie's block copolymer.

For the foregoing reasons, a *prima facie* case of obviousness cannot be established. For at least the same reasons, dependent claims 2-15, 20-22 and 42-48 are also not obvious over Clokie and Park. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1-15, 20-22 and 41-48.

IV. Claims 16-19 and 22-24 Are Not Obvious over Clokie in View of Park and in further View of Sierra

At page 6, first paragraph of the instant Office Action, claims 16-19 and 22-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Clokie in view of Park and in further view of Sierra. The Examiner is of the opinion that the subject claims are obvious in view of the combined teachings of Clokie, Park, and Sierra. Applicants respectfully traverse the rejection.

As discussed above in section III, the combination of Clokie and Park does not teach or suggest the claimed invention as recited in independent claim 1, from which claims 16-19 and 22-24 depend. The Examiner relies on Sierra for teaching bone powder or bone chips, but Sierra does not disclose the claimed carrier having both ends capped by methoxy groups. Thus, Sierra fails to remedy the deficiencies of Clokie and Park. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 16-19 and 22-24.

V. Conclusion

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments, and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below. Although no fee is believed due, the Commissioner is authorized to apply any additional charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

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By 
John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
(617) 720-9600